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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,596	08/17/2005	Masayuki Ii	084437-0184	1802

22428 7590 07/27/2010

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EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	PAPER NUMBER
1627	
MAIL DATE	DELIVERY MODE
07/27/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/510,596	II ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1627	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 July 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *NONE*.
   Claim(s) objected to: _____.
   Claim(s) rejected: *5 and 21-23*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See page 2.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627

Continuation of 11: Applicant's arguments have been considered, but not found persuasive as discussed in the previous office action, and those found below. All the rejections of record are MAINTAINED.

Applicant argues that the article in British Medical Bulletin "demonstrates that the person of ordinary skill in the art recognizes that treatment of some aspects of sepsis has repeatedly failed to demonstrate treatment of severe sepsis, such as is associated with organ failure, hypoperfusion and/or hypotension." These arguments have been considered, but not found persuasive. Ichimori et al. teach a method of treating sepsis or septic shock by administering a compound of formula (Iaa) which is same as instant formula (I), and includes instant elected compound 72. Accordingly, one of ordinary skill in the art at the time of invention would have been motivated to administer compound 72 with reasonable expectation of success of treating sepsis associated with organ failure, hypoperfusion or hypotension because Ichimori et al. teach that the compounds therein which broadly include instant compound 72 are useful in treating sepsis.

Applicant argues that "Ichimori's administration of a compound one hour before challenge with LPS is not reasonably relevant to the treatment of disease, especially as the term would be used and understood in the clinical context." These arguments have been considered, but not found persuasive. Ichimori teach that the compound therein has excellent inhibitory effect on cytokine production. Ichimore further teaches that the compounds therein are useful in the treatment of infectious diseases such as sepsis, septic shock and like. See page 85, paragraphs [0251]-[0253]. Accordingly, there is clear motivation to employ the compounds therein in treating severe sepsis, since the compounds are known to reduce infection.

Appliant argues that " Ichimori fails to show a therapeutic effect of the compound of the present invention against severe sepsis because it was not tested in animals with severe sepsis." These arguments have been considered, but not found persuasive.It is pointed out that even though Ichimiri does not provide example for severe sepsis, it has been well-established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. In re Boe, 355 F.2d 961, 148 USPQ 507, 510 (CCPA 1966); In re Lamberti, 545 F.2d 747, 750, 192 USPQ 279, 280 (CCPA 1976); In re Fracalossi, 681 F.2d 792, 794, 215 USPQ, 570 (CCPA 1982); In re Kaslow, 707 F.2d 1366, 1374, 217 USPQ 1089, 1095 (Fed. Cir. 1983). Ichimore teaches that the compounds therein are useful in the treatment of infectious diseases such as sepsis, septic shock and like. Accordingly, there is clear motivation to employ the compounds therein in treating severe sepsis, since the compounds are known to reduce infection.

Applicant's arguments that " Ichimori at most provides a motivation for experiment, but this is an insufficient basis under the law to render obvious the present claims." These arguments have been considered but not found persuasive. In contract to applicant's assertions of the rejection is based upon an "obvious to try" standard, it is well known that the ultimate conclusion of law that claimed subject matter as a whole would have been obvious under 35 USC 103 may at times properly be drawn from an inference of fact arising from prior art teachings which could be considered as inference that it would be "obvious to try" that which is claimed.
Therefore the above claims remain rejected under 35 USC 103 for reasons above and also those set forth in the Final Office action.

Appliant argues that " meeting a long-felt need is objective evidence of non-obviousness, and objective indicia of non- obviousness "is not just a cumulative or confirmatory part of the obviousness calculus but constitutes independent evidence of nonobviousness" that must be given full consideration." These arguments have been considered. Ichimori teaches that the compounds therein have higher efficacy, safety profile, and thus improved therapeutic effects in treating infections, sepsis, and septic shock. Further, the compounds taught by Ichimori have excellent inhibitory effect on cytokine production, and instant specification teacehs that the compounds that have inhibitory effect on cytokine production are useful in treating sepsis, particular severe sepsis. Thus, the compounds taught by Ichimori serve the long-felt need. Accordingly, Ichimori provides motivation to employ the compounds therein with resaonbale expectation of success of treating severe sepsis, since the compounds have excellent inhibitory effect on cytokine production, improved efficacy and safety profile than the compounds already known in the art to reduce infection, sepsis, septic shock.